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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------|---------------------|------------------|
| 10/031,478   | 07/29/2002  | Kevin Jeffrey Barnham | 113122.120          | 8704             |
| 7590   | 07/11/2005  |                       | EXAMINER            |                  |
| Hollie L Baker<br>Hale and Dorr<br>60 State Street<br>Boston, MA 02109 |             |                       | KOSAR, ANDREW D     |                  |
|  |             |                       | ART UNIT            | PAPER NUMBER     |
|  |             |                       | 1654                |                  |

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/031,478             | BARNHAM ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Andrew D. Kosar        | 1654                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 18 May 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4)  Claim(s) 1-44 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) \_\_\_\_\_ is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) 1-44 are subject to restriction and/or election requirement.

## Application Papers

- 9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date . . . .

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: . . . .

## DETAILED ACTION

Upon consideration of Applicant's remarks, filed May 18, 2005, regarding the Preliminary Amendment (January 18, 2002), the Examiner has withdrawn the previous restriction requirement in favor of the instant requirement.

**Claims 1-44** are pending and require restriction.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

**Group I, claim(s) 1-21, 29, 30 and 43**, drawn to a compound which interacts with the  $\beta$ -amyloid peptide and a composition.

**Group II, claim(s) 22-28**, drawn to a method of selecting or designing a compound which inhibits the binding of metal ions to the N-terminus of the  $\beta$ -amyloid peptide.

**Group III, claim(s) 31-42 and 44**, drawn to a method of inhibiting the binding of one or more metal ions to the  $\beta$ -amyloid peptide and a method of preventing, treating, or alleviating Alzheimer's disease.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature of Group I is 'a compound which interacts with  $\beta$ -amyloid protein' is not a contribution over the art.

Shao (July 26, 2002 PTO-1449, reference A5) teaches that, "As for the nicotine-inhibition to  $\beta$ -amyloidosis, the NMR work established that nicotine binds to the His13 and

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His14 side-chains of the Tyr10-Val24  $\alpha$ -helix, and this prevented an  $\alpha$ -helix  $\rightarrow$   $\beta$ -sheet conversion and  $\beta$ -amyloid precipitation.” [citation removed by Examiner] (page 767).

Binding of nicotine to  $\beta$ -amyloid protein at His13 and His14 inherently ‘blocks’ the N-terminus in such a way that binding of metal ions at said His residues is/are inhibited, thus the technical feature is not a contribution over the art and the claims lack unity.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The claims are generic to a myriad of compounds that interact with the  $\beta$ -amyloid peptide, including those identified in the schemes, tables, and figures of the instant specification, e.g., BRI7158 (scheme 2, page 26).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election [Please note that election of a generic, e.g., Compound of formula I, page 14, would not be fully responsive, as it would be an undue burden to search the myriad of compounds embraced by the generic].

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

As stated *supra*, Shao teaches a species of the 'compound which interacts with the  $\beta$ -amyloid peptide' and thus the species lack unity.

Further, Annex B, Part I(f) of the Administrative Instructions under PCT states that, "wherein a single claim defines alternatives (chemical or non-chemical)...the requirement of a technical interrelationship and the same or corresponding special technical features as defined in Rule 13.2, shall be considered to be met when the alternatives are of a similar nature."

The alternatives must comply with subsections (i)(A) and one of either (i)(B)(1) or (i)(B)(2), which requires that, "all alternatives have a common property or activity" and "a common structure is present, i.e., a significant structural element is shared by all of the alternatives" (B)(1) or "in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains."(B)(2).

In the instant case, the method requires that the compounds have the same activity/function (interaction with the  $\beta$ -amyloid peptide), satisfying requirement (A). However, the claim fails to satisfy either of (B)(1) or (B)(2). The claim recites no structure, thus failing to meet the requirements of (B)(1).

Further, in looking to subsection (f)(iii), it is stated that 'recognized class of chemical compounds' means that, "there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended

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result would be achieved." One of skill in the art would not recognize these divergent compounds identified in the specification, or other compounds asserted to have said activity/function, as required, to function in the context of the instantly claimed invention. Thus, the claim fails to meet the requirement of (B)(2).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-097474. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Andrew D. Kosar, Ph.D.  
Art Unit 1654

  
7/6/08  
ANISH GUPTA  
PATENT EXAMINER  
PRIMARY EXAMINER